

**REMARKS**

Reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

By this Amendment Applicants have amended claims 37 and 39. Support for the amendment to claim 37 is to be found at page 8, lines 5, 11, 16 and 18; at page 10, lines 4-9, and page 13, lines 8-9 and 30 of the as-filed specification.

The amendments to claim 39 are supported by withdrawn claims 22 and 23 as well as at page 6, line 21; page 8, line 18, and page 9, line 22 of the as-filed specification.

The claims presently before the Examiner are 37-41, inclusive.

**35 U.S.C. § 112**

In the Office Action the Examiner has rejected claim 38 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph. More specifically, the Examiner expresses the view that claim 38 recites a broad limitation allowing granules in amounts as low as 0.01% of the dough, while claim 38 (Applicants assume that here claim 37 is meant) requires at least 0.1% of granules which is the narrower statement of the range/limitation.

In Applicants' view this rejection is misplaced since the lower limit of 0.01 wt.% mentioned in claim 38 is calculated by weight of dough or batter, whereas the lower limit of 0.1 wt.% in claim 37 is calculated by weight of the granules containing composition that is used in the preparation of a dough or a batter. Clearly, these numbers are not inconsistent as, for instance, a granules containing composition that contains 50 wt.% of the granules can be used to prepare a dough or a batter containing 0.5 wt.% of these same granules (by adding the granules containing composition in an amount 1% by weight of the final dough or batter).

In view of the foregoing, the § 112, second paragraph, rejection is deemed to have been overcome and its withdrawal is solicited.

**35 U.S.C. § 103**

The Examiner has rejected claims 39-41 under 35 U.S.C. § 103(a) as unpatentable over Sharma (US 4,797,288). This rejection is respectfully traversed.

Claim 39, as amended, is now independent, and is directed to a method that produces granules containing non-lipophilic particles containing at least 0.1 wt.% of one or more functional food ingredients selected from enzymes, oxidoreductants and combinations thereof.

In contrast, Sharma teaches granules containing non-lipophilic particles in the form of a drug, a sweetener or a flavouring agent (column 1, lines 13-14; column 8, lines 25-27)

Applicants note that claim 39 defines a method of manufacturing a composition. The composition requires that the granules contained therein contain 50-90 wt.% of an agglomerate and 10-50 wt.% of an exterior lipid layer.

On page 12, lines 9-16 the benefits associated with granules having 10-50 wt.% of an exterior lipid layer are explained as follows: *The present invention offers the advantage that high payloads of non-lipophilic particles can be realised without serious leakage without using large amounts of encapsulating material, notably the discrete continuous phase and the exterior lipid layer. .... Due to the fact that the non-lipophilic particles have been partly encapsulated by the discrete continuous phase, it is feasible to achieve effective encapsulation even when applying a relatively thin exterior lipid layer.*

By contrast, Sharma specifically teaches to employ an exterior coating in amounts of about 200 to about 400% by weight of the agglomerate (column 8, lines 15-19 and claim 1).

Consequently, the method defined in amended claim 39 differs from the method taught by Sharma in that it (i) yields granules containing non-lipophilic particles that contain enzymes and/or oxidoreductants and (ii) yields granules containing 10-50 wt.% of an exterior lipid layer.

Since Sharma does not contain any reference to enzymes or oxidoreductants and since Sharma teaches away from granules in which the exterior coating represents not more than 50 wt.% of the total granule, the subject matter of present claim 39 cannot be said to be obvious therefrom.

In addition, Applicants note that the aforementioned combination of features yields a number of benefits that a person of ordinary skill in the art would not have anticipated or appreciated (see page 5, line 6 ff.):

*The methodology of the present invention offers the advantage that it enables the preparation of fat coated non-lipophilic particles that do not exhibit leakage without resorting to the use of excessive amounts of fat, in other words: the present invention provides non-leaking granulates with a high payload. Moreover, the granules according to the invention show this resistance to leakage even when exposed to conditions of (limited) shear. ...*

*The granules according to the present invention can advantageously be used for delivering the functional ingredients therein in a controlled fashion. The release of such ingredients can suitably be triggered by temperature increase, resulting in melting of the exterior lipophilic layer and/or by conditions of shear that destroy the integrity of the exterior layer. The fact that the present invention enables the preparation of coated granulates that show little leakage and a homogeneous particle size distribution offers the advantage that the release characteristics of the granulate can be tailored to the targeted application.*

*Furthermore, the invention facilitates the preparation of a uniform and homogeneous granulate in which the fat coated granules contain two or more very different particulate materials, e.g. enzymes and oxidoreductants. Finally, the invention provides an effective method for applying a fat coating to non-lipophilic particles that are irregularly shaped.*

Since Sharma fails to teach or suggest the above benefits, and the claimed method, the subject matter is deemed to distinguish over Sharma. Accordingly, the

Examiner has failed to establish a *prima facie* case of obviousness. Withdrawal of the rejection is respectfully solicited.

The Examiner has further rejected claims 37-38 under 35 U.S.C. 103(a) as unpatentable over Sharma (US 4,797,288) in view of Dustherhoft et al. (2006/0110494). This rejection is respectfully traversed.

Amended claim 37 defines a method of preparing a dough or a batter that comprises adding a bread improver composition, said bread improver composition comprising granules having an average diameter in the range of 40-290  $\mu\text{m}$  and comprising:

- a. 10-60 wt.% of a plurality of non-lipophilic particles with an average diameter in the range of 3-300  $\mu\text{m}$ , said particles containing at least 10 wt.% of one or more food components selected from the group of carbohydrates, proteins, salt and functional food ingredients and at least 0.1 wt.% of one or more functional food ingredients, said functional food ingredients being selected from the group of enzymes, oxidoreductants, acidulants, hydrocolloids, micro-organisms, flavours and combinations thereof;
- b. 15-40 wt.% of a discrete continuous phase containing at least 90 wt.% lipids, which continuous phase envelops the non-lipophilic particles and holds them together, the combination of non-lipophilic particles and the continuous phase forming an agglomerate with a diameter in the range of 30-200  $\mu\text{m}$ ; and
- c. 10-50 wt.% of an exterior lipophilic layer that encompasses the agglomerate, which lipophilic layer exhibits a slip melting point of at least 30°C.

As explained before, Sharma fails to teach granules that contain 10-50 wt.% of an exterior lipophilic layer.

In addition, Sharma fails to teach a bread improver composition containing granules.

Sharma also fails to teach a method of preparing a dough or a batter that comprises the adding of granules. In column 2, line 47 and column 8, line 32 Sharma mentions that the delivery system described therein may be useful in baked goods. Applicants note, however, that this observation does not render it obvious to add the delivery system to non-baked goods, more particularly it does not render it obvious to add said delivery system to a dough or batter prior to baking.

As a matter of fact Sharma actually teaches the importance of insuring that the delivery system should be incorporated in food products, pharmaceutical preparations, beverages, tobacco and proprietary products (column 2, lines 46-49) in such a way that the delivery system remains intact until such time that it is consumed. This conclusion can be drawn from, for instance, the following observations in Sharma:

- Column 2, lines 3-6: *The instant invention provides a drug delivery system which uniformly coats and protects the drug from moisture and subsequent hydration prior to complete ingestion*
- Column 7, lines 31-36: *The delivery system .... such that it melts and releases the core drug material within the normal body temperature range of humans having passed through the oral cavity*
- Column 9, lines 54-56: *The composite can then be added as the temperature of the mix is lowered below the melting point of the matrix ....*

The addition of a delivery system according to Sharma to a dough or a batter, followed by baking goes against the teaching of Sharma, as the baking will inevitably cause the release of the encapsulated drug, thereby yielding a baked product in which the previously encapsulated drug is no longer protected. As a result such a baked product would exhibit all the disadvantages that Sharma aims to avoid (see column 1, lines 11-13).

Dusterhoft et al. describe encapsulated bakery ingredients and the addition of such encapsulated bakery ingredients to a dough or batter.

Applicants fail to see what would have motivated a person of ordinary skill in the art to combine the teachings of Sharma and Dusterhoft et al., especially since Sharma is concerned with drug delivery systems that protect an encapsulated drug prior to ingestion (column 2, lines 3-6), whereas Dusterhoft is concerned with providing encapsulated or coated functional bakery ingredient(s) that release the bakery ingredient rapidly and in a controlled manner when said functionality is required, especially during proving of the dough (paragraph [0012]).

Since Sharma fails to provide any suggestion that the drug delivery systems described therein can be used for rapid and controlled release of functional bakery ingredients during proving of dough, Applicants traverse and take issue with the Examiner's assertion that it would have been obvious to one having ordinary skill in the art at the time of the invention to use the delivery system disclosed by Sharma in the preparation of a dough or a batter.

In addition, even if such a person of ordinary skill were to combine the teachings of Sharma and Dusterhoft et al., we fail to see how this would have lead such person to the method as defined in present claim 37. More particularly, we fail to see how Dusterhoft would have motivated a skilled person to modify the granules according to Sharma by reducing the amount of exterior coating from 200-400% by weight of the granule to 10-50% by weight of the granule.

Thus, in Applicants' view the subject matter of claims 37-38 distinguishes over the combined teaching of the art. Accordingly, it is respectfully submitted that the rejection has been overcome and should be withdrawn.

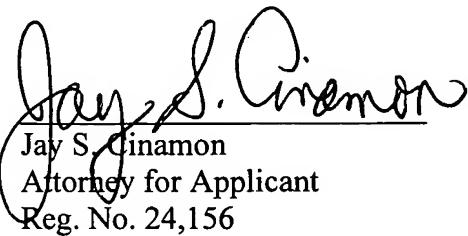
Since the rejections have been overcome, the issuance of a Notice of Allowance is solicited.

Please charge any fees which may be due and which have not been submitted herewith to our Deposit Account No. 01-0035.

Respectfully submitted,

ABELMAN, FRAYNE & SCHWAB  
Attorneys for Applicant

By

  
Jay S. Cinnamon  
Attorney for Applicant  
Reg. No. 24,156

666 Third Avenue  
New York, NY 10017-5621  
Tel.: (212) 949-9022  
Fax: (212) 949-9190